

### **REMARKS**

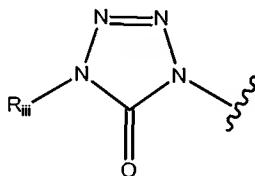
Claims 1 – 16 are pending. Claims 1-16 stand rejected under 35 USC §112, first paragraph. With the present Amendment and Reply, Applicants amend claim 1 to illustrate a HET ring as suggested by the Examiner. Applicants further amend the definition of R<sub>iii</sub> in claim 1. Support for these amendments exists throughout the specification including, but not limited to, Examples 1.11-1.13, 1.27-1.29, 1.43-1.45 and 1.58 of the specification.

No new matter is presented. Applicants address the issues identified in the Office Action in the order in which they were presented.

### **35 USC §112 First Paragraph**

The Examiner rejects claims 1-16 as lacking enablement. The Examiner notes that the specification enables a method of making the compounds of Examples 1.11-1.13, 1.27-1.29, 1.43-1.45 and 1.58 but contends the specification does not allegedly enable a method of making the claimed compounds where HET is 1,2,3,4-tetrazol-5-one. The Examiner also suggests that the intended HET ring be illustrated structurally, rather than by name, to avoid possible misinterpretation.

With the present Amendment and Reply, Applicants amend claim 1 to illustrate the HET ring as follows:



While Applicants do not acquiesce in the propriety of the Examiner's rejection, in an effort to advance prosecution Applicants further amend claim 1 to recite that R<sub>iii</sub> is C<sub>1</sub>-C<sub>3</sub>alkyl or halo-C<sub>1</sub>-C<sub>3</sub>alkyl. In view of these amendments, the claims encompass at least the compounds of Examples 1.11-1.13, 1.27-1.29, 1.43-1.45 and 1.58 which are noted explicitly by the Examiner as enabled. Applicants believe the currently pending claims are fully enabled and in condition for allowance. Applicants reserve the right to file one or more divisional or continuation applications directed to any subject matter subject to restriction or cancelled.

Despite the claim amendments presented herein and in an effort to address the Examiner's arguments, Applicants offer the following analysis of the factors set forth in *In re Wands*. In short, Applicants' analysis supports a finding that the Examiner has not met the burden of establishing a *prima facie* case. Specifically, Applicants demonstrate that the

specification does enable the skilled artisan to practice the full spectrum of the claims categorized as "Group IV" compounds in the Office Action dated April 15, 2008.

(1) Breadth of the Claims

The Examiner contends that the specification does not disclose preparation of the disclosed compounds, particularly failing to show the source of the necessary starting materials and intermediates or the methods of preparation of the required starting materials and intermediates. Applicants respectfully disagree. The instant specification contains an enabling disclosure of how to make compounds of formula (I) at paragraphs [0057]-[0075] of the published specification, including intermediates. Further, an example of how to prepare compound 1.4 (Table 1) is set forth in paragraphs [0098]-[0102] of the published specification. One of ordinary skill in the art may prepare the claimed compounds and, thus, the specification satisfies the enablement requirement.

(2) Nature of the Invention and Predictability of the Art

Applicants agree that the unpredictability in the chemical arts is high. As restated in MPEP §2164, however, the purpose of the enablement requirement is simply to ensure that the invention is communicated to the interested public in a meaningful way. To meet the requirement, the information contained in the disclosure must be sufficient to inform those skilled in the relevant art how to make and use the claimed invention. Importantly, MPEP §2164 states that enablement does not require a disclosure to enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment.

Further, when making a rejection under enablement, the PTO bears the initial burden of making a sufficient rejection. In other words, the PTO must set forth a reasonable explanation as to why it believes that the scope of the claims is not adequately enabled by the description provided. This includes providing sufficient reasons for doubting any assertions in the claims and specification as to the scope of enablement. In view of the guidance as to preparation of the claimed compounds and their intermediates that appears in the instant specification, the Examiner does not, and indeed cannot, support any specific reason as to why the present compounds could not be prepared based on the support found in the instant specification. Generalized arguments regarding the ability to make all claimed compounds are not an adequate basis for an enablement rejection.

(3) Direction/Guidance

The Examiner asserts that the guidance provided by the present specification is insufficient. The enablement requirement does not require exhaustive experimental data across the entire breadth of the claim. Rather, if those of skill in the art are adequately enabled to

make and use the invention, then §112, first paragraph is satisfied. The present specification includes a detailed description of how to make and use the compounds of the present invention, including specific synthetic guidance (paragraphs [0098]-[0102]) and biological examples (see paragraphs [0107]-[0112]). While the example at paragraphs [0107]-[0112] is directed to compound 1.4 in Table 1, one skilled in the art may prepare the claimed compounds based on the reaction conditions and starting materials disclosed in the specification. The starting material, 4-methoxyphenylhydrazine, is commercially available as a starting material and the intermediates (e.g., N-(4-methoxyphenyl)-N'-pivaloyl-hydrazine, 1-methoxy-4-(5-oxo-2-tert-butyl-3,4-diaza-1-oxa-cyclopent-2-en-4-yl)-benzene, and 1-hydroxy-4-(5-oxo-2-tert-butyl-3,4-diaza-1-oxa-cyclopent-2-en-4-yl)-benzene) are obtained as detailed in the specification. Further, one skilled in the art understands that one substituent can be replaced by another substituent during a reaction step or, in the same reaction step, replace a plurality of substituents by other substituents (see paragraph [0062] of the published specification). Thus, the claimed compounds are enabled in view of not only the specification's guidance but also in view of the knowledge of one skilled in the art.

#### (4) State of the Prior Art

The Examiner asserts that the formation of compounds is highly species-specific in organic chemistry and that unless starting materials to prepare all compounds within the scope of the claims are available, the claims are not enabled. Applicants agree that formation of organic compounds is species-specific. Based on the framework of synthetic support provided by the instant specification, however, one of ordinary skill would be equipped with the requisite knowledge to prepare the claimed compounds. The Examiner provides no evidence or scientific reasoning to support the assertions of lack of enablement in view of the both the teaching of the instant specification and prior art. Thus, the Examiner's burden has not been met.

#### (5), (6), and (7) Working Examples, Skill of Those in the Art, and Quantity of Experimentation

Again, the Examiner has not established that those skilled in the art could not prepare the claimed compounds. Such a contention is supported by the preparation example set forth in paragraphs [0098]-[0102] of the published specification. The claimed compounds can be prepared by one of ordinary skill in the art in a manner analogous to that set forth the aforementioned paragraphs.

Applicants further note that the lack of working examples, in and of itself, is not fatal to a finding of enablement. See *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). The Examiner states that "Applicants must show making all claimed compounds or limit the claims accordingly." To the contrary, the Federal Circuit has held that a

claim is not fully enabled because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *Id.* The patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. *Id.* Thus, spelling out every detail of the invention in the specification is unnecessary. *Id.* Only enough support must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation. *Id.* This threshold of enablement dictated by the Federal Circuit is met by the current specification because the claimed compounds can be prepared in a manner analogous to that described in the preparation example as discussed, *supra*.

In view of the current amendment and regarding the *Wands* factors discussed hereinabove, Applicants submit that the weight of evidence clearly supports a finding that the claims comply with the enablement requirement of 35 USC 112, first paragraph. Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

Upon entry of the amendment, the claims are believed to be in condition for allowance and such action is requested. If the Examiner has any remaining issues required for resolution, she is encouraged to telephone the undersigned for expeditious handling.

Respectfully submitted,

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